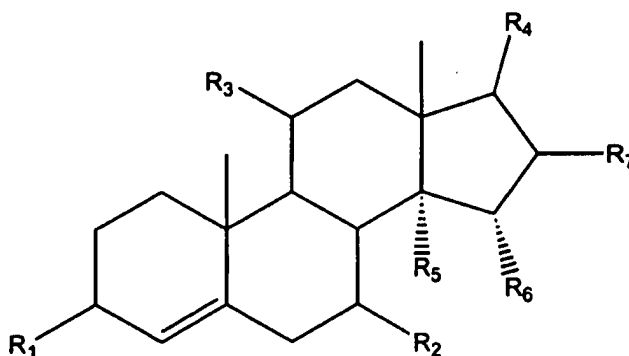


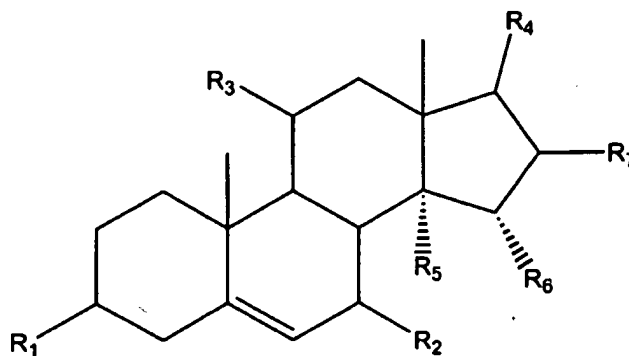
# Application 10/827,537

## WE CLAIM:

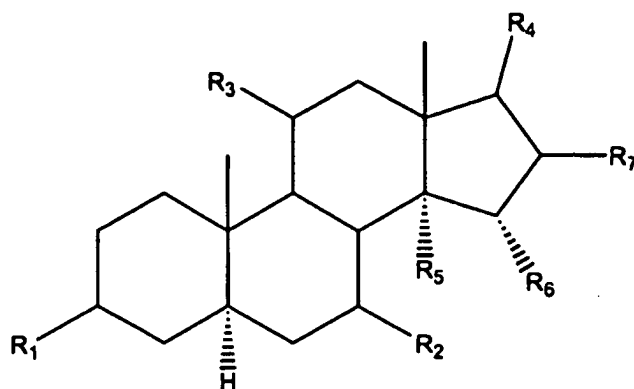
1. A composition comprising one or more long chain alcohols (policosanols) and/or their respective acids (policosanoic acids) and one or more ascorbic acid derivatives, including all biologically acceptable salts or solvates or prodrugs of at least one such derivative or of the salts or of the solvates thereof represented by the following general formulae:



I



II



III

R<sub>8</sub>-R<sub>9</sub>

IV

wherein, in formulae I, II and III, representing derivatives of androstene and androstane, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, R<sub>5</sub>, R<sub>6</sub> may individually be chosen from hydrogen, OH, carbonyl, and an ascorbyl-based moiety, and wherein at least one substituent is the ascorbyl-based moiety; and R<sub>7</sub> may be hydrogen or any halogen; and wherein, in formula IV, R<sub>8</sub> is an ascorbyl-based moiety and R<sub>9</sub> is a sterol or stanol moiety.

2. The composition of claim 1, wherein, in formula IV, R<sub>9</sub> is a phytosterol or phytostanol selected from the group consisting of sitosterol, campesterol, stigmasterol, brassicasterol (including dihydrobrassicasterol), desmosterol, chalinosterol, poriferasterol, clionasterol, ergosterol, coprosterol, codisterol, isofucosterol, fucosterol, clerosterol, nervisterol, lathosterol, stellasterol, spinasterol, chondrillasterol, peposterol, avenasterol, isoavenasterol, fecosterol, pollinastasterol, sitostanol, campestanol, stigmastanol, brassicastanol (including

dihydrobrassicastanol), desmostanol, chalinostanol, poriferastanol, clionastanol, ergostanol, coprostanol, codistanol, isofucostanol, fucostanol, clerostanol, nervistanol, lathostanol, stellastanol, spinastanol, chondrillastanol, pepostanol, avenastanol, isoavenastanol, fecostanol, and pollinastanol.

3. The composition of claim 1 wherein, in formula IV, the sterol and stanol are in either a natural or synthesized form.

4. The composition of claim 1 wherein, in formula IV, the sterol and stanol are in any one of their isomeric forms.

5. The composition of claim 1, wherein, in formula IV, the stanol is sitostanol.

6. The composition of claim 1 comprising a disodium ascorbyl stanyl phosphate composition which comprises a blend of disodium ascorbyl campestanol phosphate and disodium ascorbyl sitostanyl phosphate each in accordance with formula IV.

7. The composition of claim 1 wherein the policosanols are derived from sugar cane.

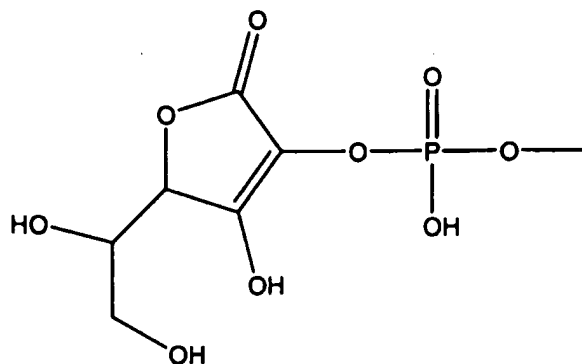
8. The composition of claim 1 wherein the policosanols are derived from Cuban sugar cane (*Saccharum officinarum*).

9. The composition of claim 1 wherein the policosanols are derived from one of rice bran wax or beeswax.

10. The composition of claim 1 wherein the policosanols are long chain alcohols comprising from 20 to 39 carbons.

11. The composition of claim 1 wherein, in each formulae, the ascorbyl-based

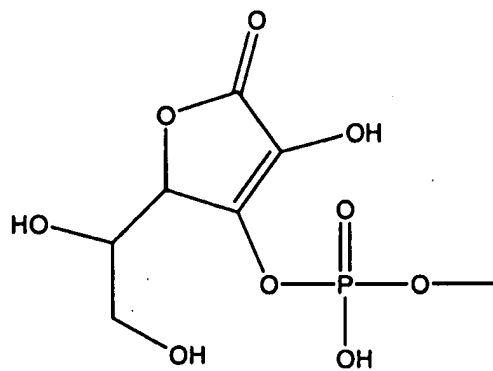
moiety is:



**V**

or one of its' biologically acceptable salts.

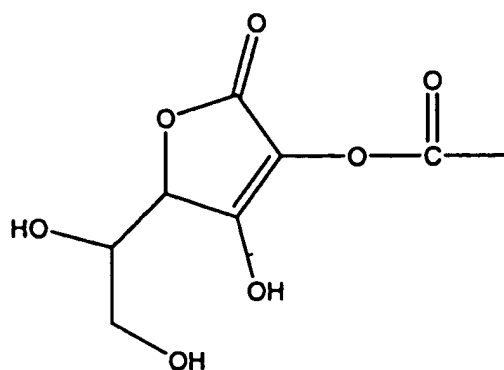
12. The composition of claim 1 wherein, in each formulae, the ascorbyl-based moiety is:



**VI**

or one of its' biologically acceptable salts.

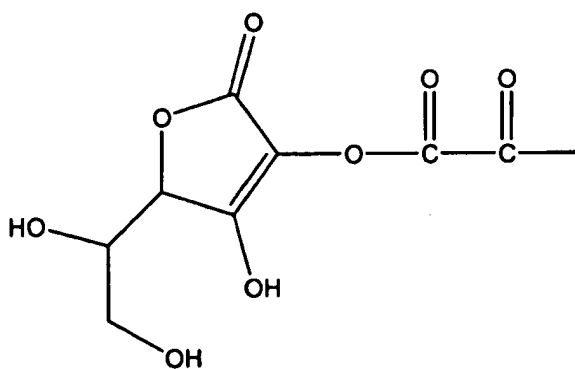
13. The composition of claim 1 wherein, each formulae, the ascorbyl-based moiety is:



**VII**

or one of its' biologically acceptable salts.

14. The composition of claim 1 wherein, in each formulae, the ascorbyl-based moiety is:

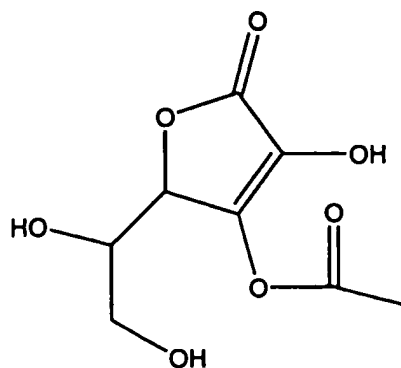


**VIII**

or one of its' biologically acceptable salts.

15. The composition of claim 1 wherein, in each formulae, the ascorbyl-based moiety is:

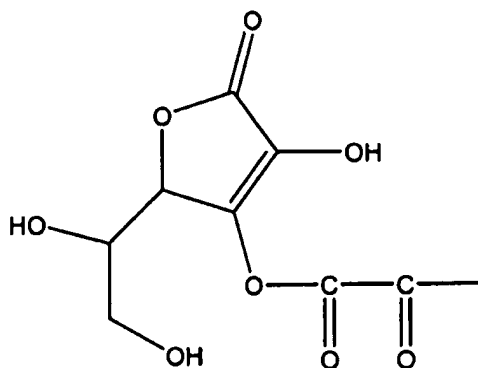
**IX**



or one of its' biologically acceptable salts.

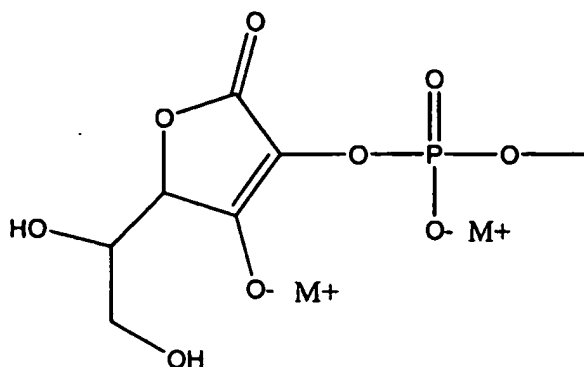
16. The composition of claim 1 wherein, in each formulae, the ascorbyl-based moiety is:

**x**



or one of its' biologically acceptable salts.

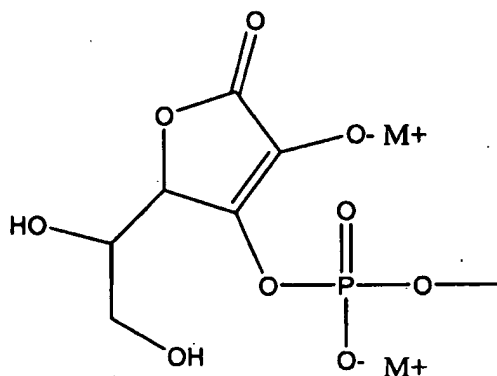
17. The composition of claim 1 wherein, in each formulae, the ascorbyl-based moiety is:



**XI**

wherein  $\text{M}^+$  is selected, independently, from the group consisting of hydrogen, metals, alkali earth metals, or alkali metals.

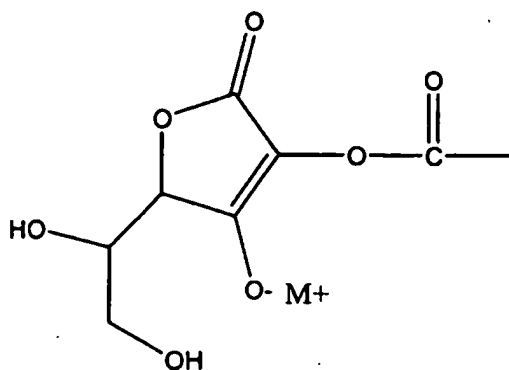
18. The composition of claim 1 wherein, in each formulae, the ascorbyl-based moiety is:



**XII**

wherein  $\text{M}^+$  is selected, independently, from the group consisting of hydrogen, metals, alkali earth metals, or alkali metals.

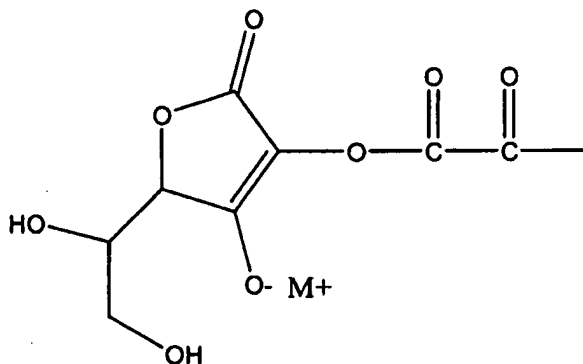
19. The composition of claim 1 wherein, in each formulae, the ascorbyl-based moiety is:



### XIII

wherein M<sup>+</sup> is selected, from the group consisting of hydrogen, metals, alkali earth metals, or alkali metals.

20. The composition of claim 1 wherein, in each formulae, the ascorbyl-based moiety is:

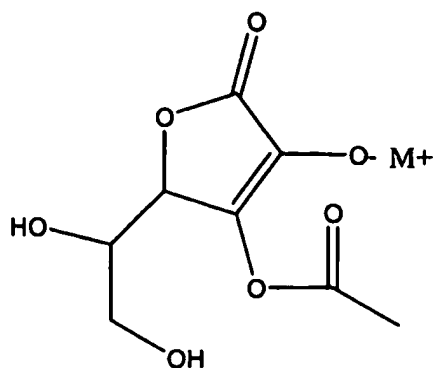


### XIV

wherein M<sup>+</sup> is selected, from the group consisting of hydrogen, metals, alkali earth metals, or alkali metals.

21. The composition of claim 1 wherein, in each formulae, the ascorbyl-based moiety is:

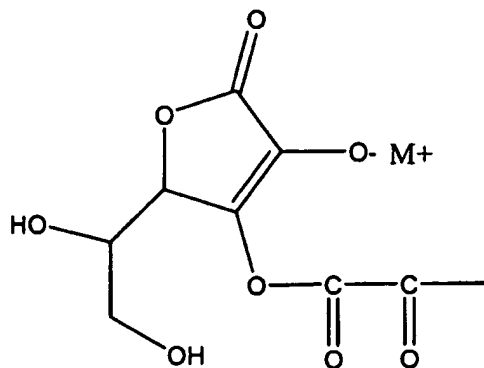




**XV**

wherein  $M^+$  is selected, from the group consisting of hydrogen, metals, alkali earth metals, or alkali metals.

22. The composition of claim 1 wherein, in each formulae, the ascorbyl-based moiety is:



**XVI**

wherein  $M^+$  is selected, from the group consisting of hydrogen, metals, alkali earth metals, or alkali metals.

23. The composition of any of claims 17 to 23, wherein  $M^+$  is selected from the group consisting of calcium, magnesium, manganese, copper, zinc, sodium, potassium and lithium.

24. The composition of claim 1 wherein, in formulae I, II and III, R1 is an ascorbyl moiety, R2, R3, R5, R6 and R7 are H, and R4 is carbonyl.

25 ~~18.~~ The composition of claim 1 wherein, in formulae I, II and III, R1 is an ascorbyl moiety, R2, R3, R5 R6 and R7 are H, and R4 is OH.

26 ~~19.~~ The composition of claim 1 wherein, in formulae I, II and III R4 is an ascorbyl moiety, R1 is OH, and R2, R3, R5, R6 and R7 are H.

27 ~~20.~~ The composition of claim 1 wherein, in formulae I, II and III R4 is an ascorbyl moiety, R1 is carbonyl, and R2, R3, R5, R6 and R7 are H.

28 ~~21.~~ The composition of claim 1 wherein, in formulae I, II and III R1 and R4 are ascorbyl moieties, and R2, R3, R5, R6, and R7 are H.

29 ~~22.~~ The composition of claim 1 wherein, in formulae I, II and III R1 and R2 are ascorbyl moieties, R3, R5, R6 and R7 are H, and R4 is OH.

30 ~~23.~~ The composition of claim 1 wherein, in formulae I, II and III R1 and R2 are ascorbyl moieties, R3, R5, R6, and R7 are H, and R4 is carbonyl.

31 ~~24.~~ The composition of claim 1 wherein, in formulae I, II and III R1 and R4 are ascorbyl moieties, R2 is OH, and R3, R5, R6 and R7 are H.

32 ~~25.~~ The composition of claim 1 wherein, in formulae I, II and III R3 is an ascorbyl moiety, R1 and R4 are carbonyl, and R2, R5, R6 and R7 are H.

33 ~~26.~~ The composition of claim 1 wherein, in formulae I, II and III R3 is an ascorbyl moiety, R1 and R4 are OH, and R2, R5, R6 and R7 are H.

34 ~~27~~ The composition of claim 1 wherein, in formulae I, II and III R5 is an ascorbyl moiety, R1 and R4 are carbonyl, and R2, R3, R6 and R7 are H.

35 ~~28~~ The composition of claim 1 wherein, in formulae I, II and III R5 is an ascorbyl moiety, R1 and R4 are OH, and R2, R3, R6 and R7 are H.

36 ~~29~~ The composition of claim 1 wherein, in formulae I, II and III R6 is an ascorbyl moiety, R1 and R4 are carbonyl, and R2, R3, R5 and R7 are H.

37 ~~30~~ The composition of claim 1 wherein, in formulae I, II and III R6 is an ascorbyl moiety, R1 and R4 are OH, and R2, R3, R5 and R7 are H.

38 ~~31~~ The composition of claim 1 wherein, in formulae I, II and III wherein R4 is an ascorbyl moiety, R1 and R2 are OH, and R3, R5, R6 and R7 are H.

39 ~~32~~ The composition of claim 1 wherein, in formulae I, II and III R4 is an ascorbyl moiety, R1 and R3 are OH, and R2, R5, R6 and R7 are H.

40 ~~33~~ The composition of claim 1 wherein, in formulae I, II and III R4 is an ascorbyl moiety, R1 and R3 are carbonyl, and R2, R5, R6 and R7 are H.

41 ~~34~~ The composition of claim 1 wherein, in formulae I, II and III R4 is an ascorbyl moiety, R1 is OH, R3 is carbonyl and R2, R5, R6 and R7 are H.

42 ~~35~~ The composition of claim 1 wherein, in formulae I, II and III R4 is an ascorbyl moiety, R1 is carbonyl, R3 is OH, and R2, R5, R6 and R7 are H.

43 ~~36~~ The composition of claim 1 wherein, in formulae I, II and III R1 is an ascorbyl moiety, R3 and R4 are OH, and R2, R5, R6 and R7 are H.

44 ~~37~~ The composition of claim 1 wherein, in formulae I, II and III R1 is an ascorbyl

moiety, R3 and R4 are carbonyl, and R2, R5, R6 and R7 are H.

45 ~~38~~ The composition of claim 1 wherein, in formulae I, II and III R1 is an ascorbyl moiety, R3 is OH, R4 is carbonyl, and R2, R5, R6 and R7 are H.

46 ~~39~~ The composition of claim 1 wherein, in formulae I, II and III R1 is an ascorbyl moiety, R3 is carbonyl, R4 is OH, and R2, R5, R6 and R7 are H.

47 ~~40~~ The composition of claim 1 wherein, in formulae I, II and III R1 is an ascorbyl moiety, R2 and R4 are OH, and R3, R5, R6 and R7 are H.

48 ~~41~~ The composition of claim 1 wherein, in formulae I, II and III R1, R2 and R4 are ascorbyl moieties, and R3, R5, R6 and R7 are H.

49 ~~42~~ The composition of claim 1 wherein, in formulae I, II and III R1 and R2 are ascorbyl moieties, R4 is carbonyl, and R3, R5, R6 and R7 are H.

50 ~~43~~ The composition of claim 1 wherein, in formulae I, II and III R1 is an ascorbyl moiety, R4 is carbonyl, R2, R3, R5, R6 are H, and R7 is a halogen.

51 ~~44~~ The composition of claim 1 wherein, in formulae I, II and III R1 and R4 are ascorbyl moieties, R2, R3, R5, R6 are H, and R7 is a halogen.

52 ~~45~~ The composition of claim 1 wherein, in formulae I, II and III R4 is an ascorbyl moiety, R1 is carbonyl, R2, R3, R5, R6 are H, and R7 is a halogen.

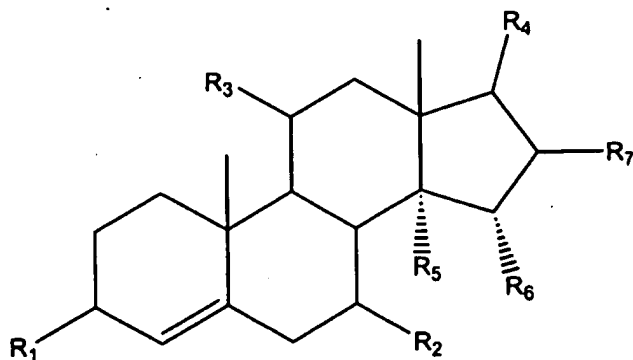
53 ~~46~~ The composition of claim 1 wherein, in formulae I, II and III R3 is an ascorbyl moiety, R4 is carbonyl, R1 is OH, R2, R5, R6 are H, and R7 is a halogen.

54 ~~47~~ The composition of claim 1 wherein, in formulae I, II and III R3 is an ascorbyl moiety, R4 is OH, R1 is carbonyl, R2, R5, R6 are H, and R7 is a halogen.

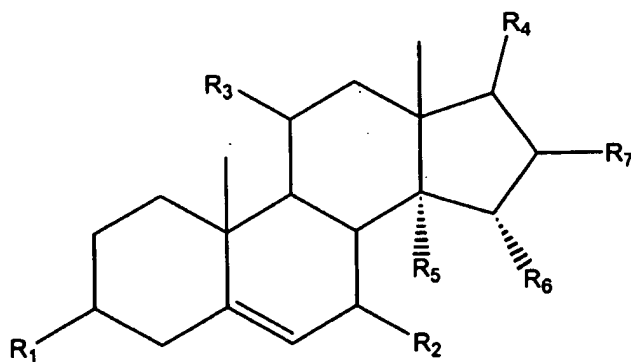
- 55 ~~42~~ The composition of claim 1 wherein, in formulae I, II and III R5 is an ascorbyl moiety, R1 and R4 are carbonyl, R2, R3, R6 are H, and R7 is a halogen.
- 56 ~~43~~ The composition of claim 1 wherein, in formulae I, II and III R5 is an ascorbyl moiety, R1 and R4 are OH, R2, R3, R6 are H, and R7 is a halogen.
- 57 ~~44~~ The composition of claim 1 wherein, in formulae I, II and III R6 is an ascorbyl moiety, R1 and R4 are carbonyl, R2, R3, R5 are H, and R7 is a halogen.
- 58 ~~45~~ The composition of claim 1 wherein, in formulae I, II and III R6 is an ascorbyl moiety, R1 and R4 are OH, R2, R3, R5 are H, and R7 is a halogen.
- 59 ~~46~~ The composition of claim 1 wherein, in formulae I, II and III R1, R3 and R4 are ascorbyl moieties, R2 and R5, R6 are H, and R7 is a halogen.
- 60 ~~47~~ The composition of claim 1 wherein, in formulae I, II and III R1, R4 and R5 are ascorbyl moieties, R2 and R3, R6 are H, and R7 is a halogen.
- 61 ~~48~~ The composition of claim 1 wherein, in formulae I, II and III R1, R2 and R4 are ascorbyl moieties, R3 and R5, R6 are H, and R7 is a halogen.
- 62 ~~49~~ The composition of claim 1 wherein, in formulae I, II and III R1, R4, R6 are ascorbyl moieties; R2, R3, and R5 are H; and R7 is a halogen.
- 63 ~~50~~ The composition of claim 1 additionally comprising one or more pharmaceutically acceptable carriers, adjuvants, excipients, binders, stabilizers, colouring agents, or stabilizers.
- 64 ~~51~~ The composition of claim 1 adapted into a pharmaceutical dosage form.

65

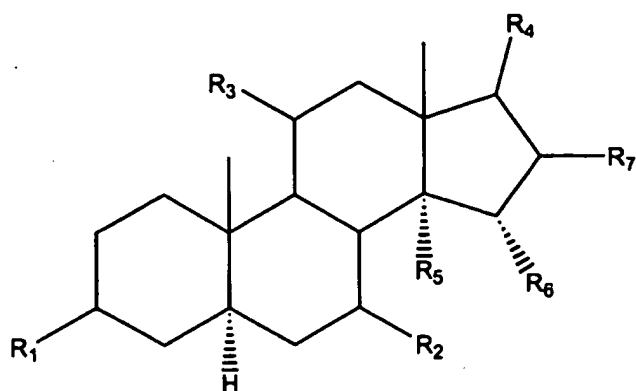
50. A method of lowering serum LDL cholesterol in an animal which comprises administering a therapeutically effective amount of a composition comprising one or more long chain alcohols (policosanols) and/or their respective acids (policosanoic acids) and one or more ascorbic acid derivatives, including salts thereof, represented by the following general formulae:



I



II



III

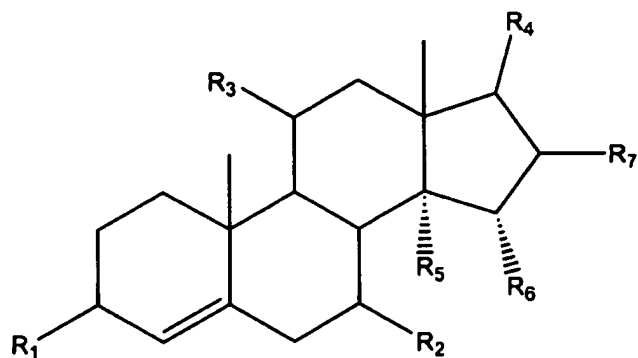
R<sub>8</sub>-R<sub>9</sub>

IV

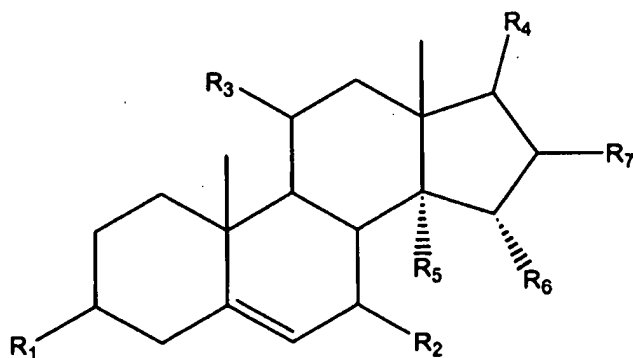
wherein, in formulae I, II and III, representing derivatives of androstene and androstane, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, R<sub>5</sub>, R<sub>6</sub> may individually be chosen from hydrogen, OH, carbonyl, and an ascorbyl-based moiety, and wherein at least one substituent is the ascorbyl-based moiety; and R<sub>7</sub> may be hydrogen or any halogen; and wherein, in formula IV, R<sub>8</sub> is an ascorbyl-based moiety and R<sub>9</sub> is a sterol or stanol moiety.

66-47 A method of reducing inflammation in an animal in need of such reduction which comprises administering a therapeutically effective amount of a

composition comprising one or more long chain alcohols (policosanols) and/or their respective acids (policosanoic acids) and one or more ascorbic acid derivatives, including salts thereof, represented by the following general formulae:

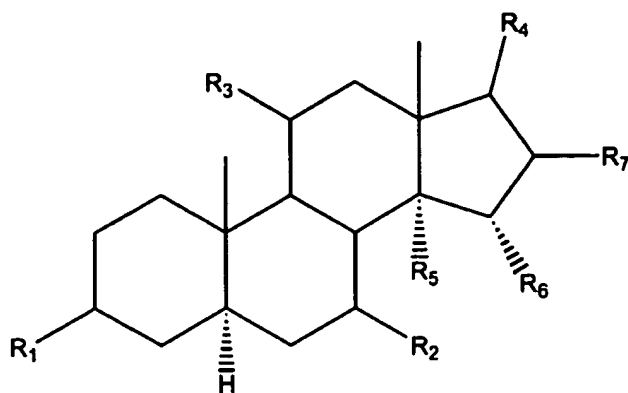


I



II





III

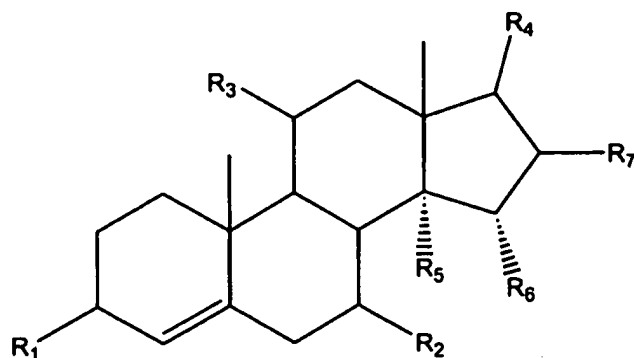
R<sub>8</sub>-R<sub>9</sub>

IV

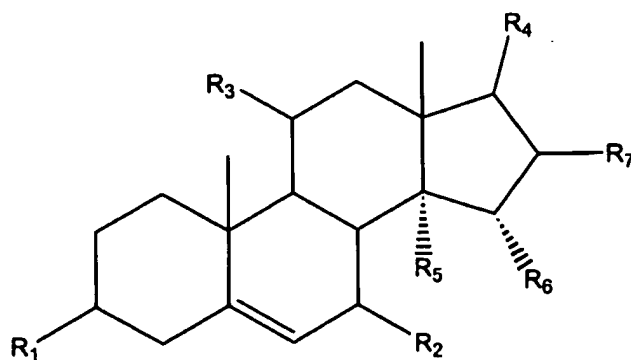
wherein, in formulae I, II and III, representing derivatives of androstene and androstane, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, R<sub>5</sub>, R<sub>6</sub> may individually be chosen from hydrogen, OH, carbonyl, and an ascorbyl-based moiety, and wherein at least one substituent is the ascorbyl-based moiety; and R<sub>7</sub> may be hydrogen or any halogen; and wherein, in formula IV, R<sub>8</sub> is an ascorbyl-based moiety and R<sub>9</sub> is a sterol or stanol moiety.

67-48 A method of modulating serum lipids and triglycerides, specifically by increasing serum HDL cholesterol and/or decreasing serum triglycerides in an animal in need of such modulation, which comprises administering a

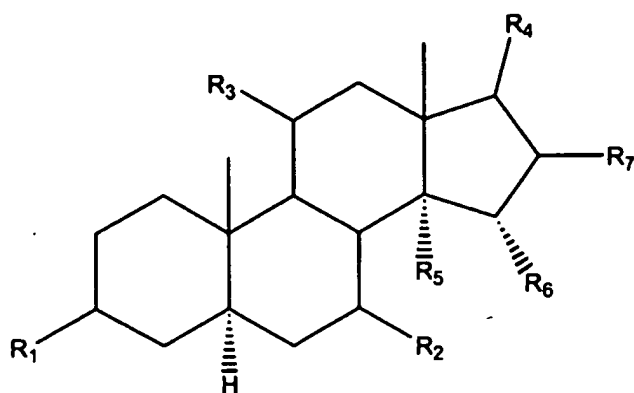
therapeutically effective amount of a composition comprising one or more long chain alcohols (policosanols) and/or their respective acids (policosanoic acids) and one or more ascorbic acid derivatives, including salts thereof, represented by the following general formulae:



I



II



III

R<sub>8</sub>-R<sub>9</sub>

IV

wherein, in formulae I, II and III, representing derivatives of androstene and androstane, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, R<sub>5</sub>, R<sub>6</sub> may individually be chosen from hydrogen, OH, carbonyl, and an ascorbyl-based moiety, and wherein at least one substituent is the ascorbyl-based moiety; and R<sub>7</sub> may be hydrogen or any halogen; and wherein, in formula IV, R<sub>8</sub> is an ascorbyl-based moiety and R<sub>9</sub> is a sterol or stanol moiety.

68 49. The composition of claim 1 comprising from 10% to 80% by weight of component A [one or more long chain alcohols (policosanols) and/or their respective acids (policosanoic acids)] and from 1% to 70% by weight of component

B [one or more ascorbic acid derivatives].

- 69-50. The composition of claim 1 comprising from 20% to 70% by weight of component A [one or more long chain alcohols (policosanols) and/or their respective acids (policosanoic acids)] and from 10% to 40% by weight of component B [one or more ascorbic acid derivatives].
- 70-51. The composition of claim 1 wherein the ratio, by weight, of component A [one or more long chain alcohols (policosanols) and/or their respective acids (policosanoic acids)] to component B [one or more ascorbic acid derivatives] is from 1:1 to 50:1.
- 71-52. The composition of claim 1 wherein the ratio, by weight, of component A [one or more long chain alcohols (policosanols) and/or their respective acids (policosanoic acids)] to component B [one or more ascorbic acid derivatives] is from 2:1 to 20:1.
- 72-53. The composition of claim 1 wherein, in the policosanol component, greater than 90% by weight of alcohols are C<sub>20</sub> or longer.
- 73-54. The composition of claim 1 wherein the policosanol component comprises greater than 50% by weight of octacosanol(C<sub>28</sub>).
- 74-55. The composition of claim 1 wherein, in the policosanoic acid component, greater than 90% by weight of acids are C<sub>20</sub> or longer.
- 75-56. The composition of claim 1 wherein the policosanoic acid component comprises greater than 50% by weight of octacosanoic acid(C<sub>28</sub>).
- 76-57. The composition of claim 1 wherein the policosanoic acid component comprises greater than 60% by weight of octacosanoic acid(C<sub>28</sub>).

77-58. The composition of claim 1 comprising at least 60% by weight octacosanol, from 9-15% triacontanol and from 4-10% hexacosanol.